

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

LELA KING,

Plaintiff,

v.

ETHICON, INC, *et al.*,

Defendants.

Civil Action No. 21-17983 (MAS) (DEA)

MEMORANDUM OPINION

SHIPP, District Judge

This matter comes before the Court on Defendants Johnson & Johnson (“J&J”) and Ethicon, Inc.’s (“Ethicon”) (together, “Defendants”) Motion to Dismiss Plaintiff Lela King’s (“King”) First Amended Complaint (the “FAC,” ECF No. 14). (ECF No. 18.) King opposed (ECF No. 22), and Defendants replied (ECF No. 23). The Court has carefully considered the parties’ submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons stated below, the Court grants Defendants’ Motion.

I. BACKGROUND¹

On October 1, 2021, King brought this action in connection with injuries she allegedly sustained from a pelvic mesh surgical product, the TVT, that Defendants manufacture. (*See generally* Compl., ECF No. 1.) The Complaint asserted the following causes of action: strict

¹ The Court adopts the factual background as recited in its June 29, 2022, Memorandum Opinion (the “First Opinion,” ECF No. 12) and only provides additional background and procedural information where relevant for the instant Motion. For the purpose of considering the instant Motion, the Court accepts all factual allegations in the Amended Complaint as true. *See Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

liability for failure to warn (Count I); strict liability for defective manufacture and design (Count II); negligence (Count III); negligent misrepresentation (Count IV); fraud (Count V); fraudulent concealment (Count VI); constructive fraud (Count VII); violation of the New Jersey Consumer Protection Act (Count VIII); and gross negligence (Count IX). (*See id.* 23-56.)

On November 8, 2021, Defendants moved to dismiss Counts I–II and IV–IX for failure to state a claim, pursuant to Federal Rule of Civil Procedure 12(b)(6).² (ECF No. 8; *see* First Op. 1.) In addition, Defendants moved to dismiss Count III with respect to all theories of negligence asserted therein except for design defect and failure to warn, for which Defendants conceded that the Complaint stated a claim. (*See* First Op. 1.)

On June 29, 2022, the Court first dismissed Counts I and II with prejudice, as the governing state law does not recognize claims for strict liability. (*Id.* 1-2.) Next, the Court dismissed Count III with respect to all negligence claims except design defect and failure to warn, which the Court allowed to proceed because, as mentioned, Defendants did not challenge them. (*Id.* 2, 6.) The Court then dismissed Count IV with prejudice, as the controlling law does not recognize claims for negligent misrepresentation in a personal injury action. (*Id.* 2.) Finally, the Court dismissed Counts V-IX without prejudice, but gave King leave to amend those counts within thirty days of the date of the accompanying Order. (*Id.*)

On July 29, 2022, King filed the instant FAC. (*See generally* FAC.) The FAC asserts claims against Defendants for negligent failure to warn and design defect (Count I); fraud (Count II); fraudulent concealment (Count III); violation of the North Carolina Consumer Protection Act (Count IV); and gross negligence (Count V). (*See id.* 23-57.) King seeks compensatory and punitive damages, among other demands. (*Id.* ¶¶ 190-92.)

² Hereafter, all references to a “Rule” or “Rules” refer to the Federal Rules of Civil Procedure.

Now before the Court is Defendants' Motion to Dismiss under Rules 12(b)(6) and 9(b). (ECF No. 18.) In particular, Defendants seek to dismiss Counts II-V of the FAC. (Defs.' Moving Br. 1, ECF No. 17.) The Motion is ripe for resolution.

II. LEGAL STANDARD

Rule 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). A district court conducts a three-part analysis when considering a motion to dismiss pursuant to Rule 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011), *as amended* (June 6, 2011). "First, the [C]ourt must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" *Id.* (alteration in original) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must accept as true all of a plaintiff's well-pleaded factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). In doing so, however, the court is free to ignore legal conclusions or factually unsupported accusations that merely state "the-defendant-unlawfully-harmed-me." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). On a motion to dismiss for failure to state a claim, the "defendant bears the burden of showing that

no claim has been presented.” *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

III. DISCUSSION

Defendants move to dismiss Counts II-V. (Defs.’ Moving Br. 1.) The Court discusses these counts below.

A. King Fails to Meet the Heightened Pleading Standard of her Fraud-Related and Consumer Protection Claims.

The Court begins with King’s fraud and consumer protections claims: Counts II-IV. Defendants contend that the FAC does not cure the deficiencies outlined in the First Opinion, in which the Court noted, among other things, that King’s original Complaint “fail[ed] to adequately plead the place or manner of the misrepresentations because she d[id] not ‘identify or cite any particular document or statement,’” and further, that she “fail[ed] to plead with any particularity the time when Defendants allegedly made misleading statements.” (First Op. 12.) The Court agrees.

As set forth in the First Opinion, to state a claim for fraud or fraudulent concealment in North Carolina,³ a plaintiff must plausibly allege “a ‘(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party.’” *Topshelf Mgmt., Inc. v. Campbell-Ewald Co.*, 117 F. Supp. 3d 722, 726 (M.D.N.C. 2015) (quoting *Forbis v. Neal*, 361 N.C. 519, 526-27 (2007)); *see also Hunter v. Guardian Life Ins. Co. of Am.*, 593 S.E.2d 595, 599 (N.C. Ct. App. 2004) (applying the same elements). The heightened pleading standard under Rule 9(b) applies to King’s fraud claims, including her consumer protection claim. (First Op. 11, 16);

³ The Court notes, once more, that the parties agree that North Carolina substantive law applies to King’s claims. (First Op. 5.)

see Topshelf Mgmt., 117 F. Supp. 3d at 726; *Gaston v. PBI Gordon Corp.*, No. 13-891, 2014 WL 4114324, at *4 (M.D.N.C. Aug. 20, 2014); *Bumpers v. Cmty. Bank of N. Va.*, 367 N.C. 81, 88 (2013) (outlining, as elements of a prima facie unfair and deceptive trade practices claim, that “a plaintiff must show: (1) the defendant committed an unfair or deceptive act or practice, (2) the action in question was in or affecting commerce, and (3) the act proximately caused injury to the plaintiff”); *see also* N.C. Gen. Stat. § 75-1.1 *et seq.*

Here, the Court finds that King fails to adequately plead her fraud, fraudulent concealment, and consumer protection claims with particularity. As for the identity of the person(s) making the misrepresentations, the FAC largely alleges “Defendants” without specifying which of the two Defendants was responsible for the alleged fraudulent assertions and omissions, much less any of the individuals responsible for the fraudulent statements and concealed material information. (*See, e.g.*, ¶ 146 (“Throughout the relevant time period[s], Defendants knew that their [p]elvic [m]esh [p]roduct was defective and unreasonably unsafe for their intended purpose.”).) While King avers that “these entities are intertwined in such a way that attributes the actions of Ethicon to [J&J], and vice versa,” district courts routinely find that “Rule 9(b) is not satisfied where a plaintiff . . . vaguely attributes the alleged fraudulent statements to ‘defendants.’” (*See* Pl.’s Opp’n Br. 8, ECF No. 22); *Riachi v. Prometheus Grp.*, 822 F. App’x 138, 142 (3d Cir. 2020).

In addition, King fails to detail with specificity the precise contents of the fraudulent statements. In response to this point, King relies heavily on ¶ 111 of the FAC, which explains that Ethicon’s false and fraudulent representations included, for example, the underreporting and withholding of information from the Food and Drug Administration (“FDA”) and representations to physicians and members of the general public that the TVT was “safe and effective.” (FAC ¶ 111; Pl.’s Opp’n Br. 9-10.) But King fails to identify, for instance, *what* information Ethicon

allegedly withheld. Notably, these are the same false and fraudulent representations that King previously relied upon in the original Complaint, and which the Court previously rejected as inadequately pled. (*See* Compl. ¶ 127; First Op. 11-12.) The Court, once more, agrees with the numerous other courts that have dismissed similarly generalized fraud allegations against Defendants. *See, e.g., Blair v. Johnson & Johnson*, No. 19-333, 2020 WL 1172715, at *6 (W.D. Ky. Mar. 11, 2020) (finding insufficient general allegations concerning representations that the product was safer and more effective than other products and procedures); *Hernandez v. Johnson & Johnson*, 2021 WL 320612, at *5 (E.D. Wash. Jan. 8, 2021) (finding insufficient general allegations concerning representations that certain mesh products were “safe, effective, [and] reliable”); *Baca v. Johnson & Johnson*, No. 20-01036, 2020 WL 6450294, at *5 (D. Ariz. Nov. 2, 2020) (finding insufficient allegations that fail to specify “the specific content” of the allegedly misleading statements); *House v. Bristol-Myers Squibb Co.*, No. 15-894, 2017 WL 55876, at *8 (finding that vague representations that the drugs “had been tested and found to be safe and effective for the treatment of diabetes” and “were safer than other alternative medications” insufficient under Rule 9(b)). King makes a similarly vague allegation that Defendants violated the North Carolina Consumer Protection Act “by knowingly and falsely representing that Defendants’ [p]elvic [m]esh [p]roduct was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous” (FAC ¶ 167.) This is yet another example of the type of speculative and conclusory statement that fails to state a claim for relief under the heightened pleading standard.

The FAC fails to cure other previously identified deficiencies as well. For example, the Court explained in the First Opinion that King failed to identify or cite to any particular document or statement which allegedly contained misrepresentations; instead, she generically pointed to

documents, brochures, and promotional materials. (First Op. 12.) The FAC similarly fails to specifically identify *where* Defendants made the fraudulent statements. Again, King points to “uniform promotional materials” and “product brochures and pamphlets.” (FAC ¶¶ 133, 167; Pl.’s Opp’n Br. 8-9.) And King’s claim that Defendants’ conduct took place “[a]t all times relevant to this matter” and “[t]hroughout the relevant time period” still does not provide adequate notice to Defendants as to *when* the allegedly fraudulent conduct took place, despite King specifying the exact date of her implantation. (FAC ¶¶ 52, 58, 146.) In sum, these broad allegations do not pass muster under the heightened pleading standard.

In light of these deficiencies, the Court dismisses Counts II-IV for failure to satisfy Rule 9(b).

B. King Fails to Adequately Plead her Gross Negligence Claim.

Next, and finally, Defendants move to dismiss King’s gross negligence claim: Count V. Defendants contend that the Court should dismiss this claim because King has not alleged sufficient facts that would plausibly establish the essential elements of her claim. (Defs.’ Moving Br. 5.)⁴ The Court agrees.

Under North Carolina law, a “successful claim for gross negligence requires proof of wanton conduct,” and “[w]illful and wanton conduct is defined as ‘the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage, or other harm.’” *Vanhoy v. Am. Int’l*

⁴ Defendants also contend that dismissal of this claim is appropriate in light of the fact that the TVT remains FDA-approved to this day, citing *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, No. 16-2734, 2021 WL 1041017, at *5 (N.D. Fla. Feb. 10, 2021), which found that allegations that a drug was unsafe could not be reconciled with fact that the drug “is still on the market.” (Defs.’ Moving Br. 5.) The Court agrees with King, however, that a ruling on the current FDA status of Defendants’ products and the meaning of FDA clearance is premature at this stage of the proceedings. (See Pl.’s Opp’n Br. 16.)


Indus., 2018 WL 5085712, at *3 (M.D.N.C. Oct. 18, 2018), *report & recommendation adopted*, 2018 WL 6731672 (M.D.N.C. Nov. 5, 2018) (quoting N.C. Gen. Stat. § 1D-5(7)). “[T]he difference between [negligence and gross negligence] is not in degree or magnitude of inadvertence or carelessness, but rather is intentional wrongdoing or deliberate misconduct affecting the safety of others.” *Yancy v. Lea*, 550 S.E.2d 155, 158 (N.C. 2001).

Here, the FAC fails to plausibly allege wanton conduct. Plainly, King fails to allege sufficient facts that Defendants knowingly misled her physician as to risks associated with the TVT. King points to certain statements in the FAC as examples of deliberate misconduct affecting the safety of others, including the following allegations: “Defendants have consistently underreported and withheld information about the propensity of their [p]elvic [m]esh [p]roducts . . . to fail and cause injury”; Defendants “suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others”; and “in spite of these risks, Defendants continued to market their pelvic mesh devices.” (Pl.’s Opp’n Br. 12-13; FAC ¶¶ 31, 36, 75.) Yet as the Court noted in the First Opinion, and reiterates today, these, and other similar allegations, “are no more than conclusions.” (First Op. 19); *Bistran v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). The Court is still unable to answer basic questions as to what factual content Defendants knowingly failed to disclose that was associated with the TVT, apart from King’s vague references to statements on “safety and quality,” and how Defendants knew of these risks in the first place. (See FAC ¶ 148.) Such mere speculation cannot survive the standard set forth in *Twombly*. See 550 U.S. at 570; see also *Cofresi v. Medtronic, Inc.*, 450 F. Supp. 3d 759, 768 (W.D. Tex. 2020) (dismissing gross negligence claim in polypropylene mesh case where the plaintiff failed to plead sufficient facts “to show that [d]efendant Ethicon acted with an extreme

degree of risk or was consciously indifferent to the safety of others by creating the [p]rolene [m]esh in question”). The Court, accordingly, dismisses Count V under Rule 12(b)(6).

IV. CONCLUSION

For the foregoing reasons, the Court grants Defendants’ Motion to Dismiss as to Counts II-V. The Court will enter an order consistent with this Memorandum Opinion.



MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE